No. 96-1405

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM 1996

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,
Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

JOYCE OSHODI, individually and as mother and next friend of KENNETH OSHODI, a minor,
Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
Petitioner,

v.

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,
Respondents.

On Petition for Writ of Certiorari to the Appellate Court of Illinois, First District

RESPONDENTS' BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Medical Device Amendments of 1976 preempt state law claims based on general obligations imposed on manufacturers when Class III medical devices which have obtained pre-market approval or investigational device exemptions are involved.

TABLE OF CONTENTS

	PAGE
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	iii
APPLICABLE STATUTES AND RULES	iv
RESPONDENTS' BRIEF IN OPPOSITION	1
STATEMENT OF THE CASE	1
THE MEDICAL DEVICE AMENDMENTS OF 1976	4
ARGUMENT	6
I.	
THE PREEMPTION ANALYSIS ESTABLISHED IN *MEDTRONIC* SUPPORTS A FINDING AGAINST PRE-EMPTION	6
A. The IDE and PMA processes do not constitute "specific requirements" under the MDA	6
B. The general duties imposed by the state law actions do not constitute "specific requirements" for a "particular device"	7
C. 360k does not pre-empt state requirements that are equal to, or substantially identical to, requirements imposed by or under the Act	9
II.	
CONGRESSIONAL GOALS UNDERLYING THE ENACTMENT OF THE MDA WOULD NOT BE COMPROMISED IF THERE WERE NO PRE-EMPTION	10
CONCLUSION	11

TABLE OF AUTHORITIES

Cases: PAGE

Armstrong v. Optical Radiation Corp., 57 Cal.Rptr. 2d 763 (Cal.Ct.App. October 29, 1996) 9

Connelly v. Iolab Corp., 927 S.W.2d 848 (Mo. 1996) 9

Kennedy v. Collagen Corp., 67 F.3d 1453 (CA 9, 1995) 7

Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996) .. *passim*

Walker v. Johnson & Johnson, 217 Mich. App. 705 (1996) 7

Statutes:

21 U.S.C. §360k(a) (Supp. 1992) ..... iv, 6

APPLICABLE STATUTES AND RULES

This case involves §360k(a) of the Medical Device Amendments of 1976, which provides as follows:

> (a) Except as provided in subsection (b) of this Section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a) (Supp. 1992).

RESPONDENTS' BRIEF IN OPPOSITION

Respondents request that this Court deny the petition for writ of certiorari seeking review of an opinion of the Appellate Court of Illinois for the First Judicial District.

STATEMENT OF THE CASE

This case consists of three separate cases, *Kernats v. SIMS*, *Oshodi v. SIMS* and *Williams v. SIMS*, which were consolidated on appeal due to a similarity of issues. In each of these cases, the minor plaintiff's mother underwent chorionic villus sampling ("CVS") during pregnancy. CVS is a medical procedure in which fetal tissue samples are obtained during the first trimester and tested for genetic abnormalities. The minor plaintiffs were subsequently born with limb deformities.

Respondents filed these cases in the Circuit Court of Cook County, Illinois, against Smiths Industries Medical Systems, Inc. ("SIMS"), which manufactured, distributed and sold the CVS catheter used in the procedure. Respondents' claims were based upon theories of strict products liability, common law negligence, and breach of express and implied warranties.

SIMS filed motions for summary judgment on the grounds that they were pre-empted by the Medical Device Amendments of 1976 ("MDA"). 21 U.S.C. §360c-360l. The Circuit Court of Cook County granted the motions for summary judgment finding that respondents' claims had been pre-empted.

Respondents appealed to the Illinois Appellate Court, First Judicial District. Relying on *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996), the Illinois Appellate Court found that respondents' state law claims were not pre-empted by the MDA. The opinion of the Appellate Court

of Illinois is reported at 283 Ill.App.3d 455, 669 N.E.2d 1300 (1st Dist. 1996).

In *Medtronic,* the recipient of a pacemaker, which was a Class III medical device and had been approved for marketing under the MDA as a device substantially similar to devices already on the market, brought an action against the manufacturer of the pacemaker asserting claims of negligence and strict liability. This Court held that none of the plaintiffs' common law claims were pre-empted by the MDA.

In determining the extent to which the MDA pre-empts state law claims, this Court noted that while §360k(a) is an express pre-emption provision, the scope of federal pre-emption under §360k is ambiguous. This ambiguity, together with Congress' express grant of authority to the Food and Drug Administration ("FDA") to implement the MDA, provided a "sound basis" for giving substantial weight to the agency's view of the statute. 116 S.Ct. at 2256.

The FDA regulations provide that state requirements are pre-empted "'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.' 21 C.F.R. §808.1(d) (1995)." *Id.* at 2257. They further provided that the statute "is not intended to pre-empt 'State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair practices in which the requirements are not limited to devices.' §808.1(d)(1)." *Id.*

Based on the language of the statute and the FDA regulations, this Court concluded that in order for pre-emption to occur, certain criteria must be met. First, federal requirements "must be 'applicable to the device'

in question"; they pre-empt state law "only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'" *Id.* at 2257.

Second, the state requirements "must be 'with respect to' medical devices and 'different from, or in addition to' federal requirements." *Id.* at 2257. State requirements "must also relate 'to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device'". *Id.* State requirements of "general applicability" "are not pre-empted except where they have 'the effect of establishing a substantive requirement for a specific device.'" *Id.* Thus, in order to determine whether there is pre-emption, a "careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement" is necessary. *Id.* at 2257-58.

Applying this analysis, the Illinois Appellate Court held that, despite the fact that the medical device in question had been granted pre-market approval ("PMA"), the respondents' negligence, strict liability, and breach of implied warranty claims were not pre-empted because those claims were based upon "general obligations" applicable to all product manufacturers. The Court further held that respondents' breach of express warranty claims were not pre-empted because the assertions forming the bases of the breach of express warranty claims arose from SIMS' own express representations, not by a state-imposed duty. Since express warranties by a manufacturer were not state "requirements", they fell outside of the scope of §360k.

THE MEDICAL DEVICE AMENDMENTS OF 1976

The present case involves the scope of the preemption provision contained in the MDA. The MDA classifies medical devices as Class I, II or III devices. 21 U.S.C. 360c(a). The degree of danger posed to the public by the medical device determines its classification. Class III medical devices, such as the CVS catheter in question, present "a potential unreasonable risk of illness or injury" and are the most heavily regulated. 21 U.S.C. §360c(a)(1)(C)(II).

In order to market a Class III medical device, a manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. 21 U.S.C. §360e(d)(2). This is accomplished by obtaining pre-market approval. To obtain pre-market approval for a Class III device, a manufacturer must submit an application which includes a bibliography of all reports concerning the device's safety and effectiveness, an outline of the device's components and properties, a description of the manufacturing process, safety data, samples of the device, copies of all proposed labeling, and any other information of the FDA requests. 21 U.S.C. §360e(c)(1). See also 21 C.F.R. §814.20. The application is referred to an advisory panel which studies the applications and submits a report and recommendation respecting approval. 21 U.S.C. §360e(c)(2). The FDA may withdraw its approval if it determines that a device previously approved is unsafe or ineffective. 21 U.S.C. §360e(c).

Not all Class III devices have received PMA approval because of two exceptions to the PMA requirement. The statute includes a grandfather provision which allows pre-1976 medical devices to remain on the market until such time as the FDA initiates and completes the

requisite PMA. See 21 U.S.C. §360e(b)(1)(A); 21 C.F.R. §814.1(c)(1). The MDA allows devices that are "substantially equivalent" to preexisting devices to avoid the PMA process so as to prevent grandfathered devices from monopolizing the market. See 21 U.S.C. §360e(b)(1)(B). *Medtronic*, 116 S.Ct. at 2247.

Manufacturers of "substantially equivalent" Class III devices must submit to a limited form of review known as "pre-market notification" or the 510(k) process, which allows the device to be marketed without further regulatory analysis if the FDA decides that it is "substantially equivalent" to a preexisting device. *Id.*

A second exception, called the "Investigational Device Exception", exempts investigational devices from the PMA process in order to encourage the development of devices. 21 U.S.C. §360j(g). Although investigational devices are not subject to the rigorous PMA process, they are subject to other regulations which set forth procedures for determining whether they are safe and effective. To obtain approval under the IDE, a manufacturer must submit an application which includes prior investigations, a description of the manufacturing process and control data, among other information. 21 U.S.C. §§360e, 360j(g). Based on the information submitted, the FDA will approve the device under the IDE unless the risks are not outweighed by the benefits, the investigation is scientifically unsound or there is reason to believe the device is ineffective. 21 C.F.R. §812.30.

ARGUMENT

I.

THE PREEMPTION ANALYSIS ESTABLISHED IN *MEDTRONIC* SUPPORTS A FINDING AGAINST PREEMPTION.

In *Medtronic* this Court considered the preemption issue with respect to a device which had been marketed pursuant to the 510(k) process. Although IDE and PMA Class III medical devices are subjected to different processes than are "substantially equivalent" devices, the preemption analysis established by this Court in *Medtronic* supports a finding against preemption.

A. The IDE and PMA processes do not constitute "specific requirements" under the MDA.

The MDA contains an express preemption clause, 21 U.S.C. § 360k(a), which provides:

> (a) Except as provided in subsection (b) of this Section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a) (Supp. 1992).

Section 360k(a) expressly provides that a federal requirement must be "applicable to the device" in question before it has any preemptive effect. 21 U.S.C. §360k(a). According to FDA regulations, federal requirements preempt state law "only" if they are "specific counterpart

regulations" or "specific" to a "particular device." 21 C.F.R. §808.1(d).

The IDE and PMA processes, however, consist of general requirements applicable to all Class III medical devices; they are not device-specific. As noted by several courts, the fact that the pre-market approval process involves specific requirements "must not be confused with the pre-market approval requirement itself acting as a specific requirement." (*Walker v. Johnson & Johnson*, 217 Mich. App. 705, 714 (1996), quoting *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (CA 9, 1995).) Thus, these processes are not "specific requirements" applicable to a "particular device" sufficient to trigger preemption.

B. The general duties imposed by the state law actions do not constitute "specific requirements" for a "particular device".

Even if the IDE and PMA processes did constitute "specific" federal requirements, preemption is nonetheless not warranted.

In *Medtronic,* this Court rejected the argument that any common law cause of action is a "requirement" which imposed duties "different from, or in addition to" the standards the FDA had promulgated in response to mandates under the FDA. *Medtronic,* 116 S.Ct. at 2251. Rather, this Court noted that the term "requirement" as used in §360k appears to presume that the State is imposing a specific duty upon the manufacturer. *Id.* Specifically, the language of the statute suggest that its focus is "device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries." *Id.* at 2252.

Even were state tort law to constitute a "requirement" under the statute, because the state law requirements were not specifically developed "with respect to" medical devices, pre-emption is not warranted. See *Medtronic*, 116 S.Ct. at 2258.

State requirements must be "with respect to" medical devices and "different from, or in addition to" federal requirements. *Id.* at 2257. State requirements must also relate to the "safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Id.* at 2257. State requirements of "general applicability" "are not pre-empted except where they have 'the effect of establishing a substantive requirement for a specific device.'" *Id.*

Respondents' common-law claims based on the manufacture of the CVS catheter, the failure to warn, and inadequate instructions are "general obligations" applicable to all manufacturers. Respondents' claims based on defective design and inadequate testing allege that SIMS defectively designed and failed to adequately test the CVS catheter. While these allegations may relate to the specific medical device in question, they similarly arise from "general duties applicable to every manufacturer" as does the implied warranty of merchantability claim. The express warranty claims do not arise from a state-imposed duty.

As explained by this Court in *Medtronic*:

> "These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape pre-emption, not because the source of the duty is judge-made common-law rule, but

> rather because their generality leaves them outside the category of requirements that §360k envisioned to be 'with respect to' specific devices . . ." *Medtronic*, 116 S.Ct. at 2258.

Since the state law claims are not requirements specifically established for medical devices, they are not pre-empted under the MDA. See *Connelly v. Iolab Corp.*, 927 S.W.2d 848, (Mo. 1996); *Armstrong v. Optical Radiation Corp.*, 57 Cal.Rptr. 2d 763 (Cal.Ct.App. October 29, 1996).

C. 360k does not pre-empt State requirements that are equal to, or substantially identical to, requirements imposed by or under the Act.

Even if specific federal "requirements" exist with respect to the CVS catheter, and even if state common law can be considered a "requirement" under §360k, the state requirement is not pre-empted unless it is "different from, or in addition to," the federal requirement. §360k(a)(1).

The regulations promulgated by the FDA expressly support the conclusion that §360k does not pre-empt state or local requirements "that are equal to, or substantially identical to, requirements imposed by or under the act." 21 C.F.R §808.1(d)(2) (1995). In *Medtronic*, this Court found that "[n]othing in §360k denies [the States] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Medtronic*, 116 S.Ct. at 2255. Thus, to the extent respondents' claims are for violations of common law duties which parallel federal requirements, they are not pre-empted.

II.

CONGRESSIONAL GOALS UNDERLYING THE ENACTMENT OF THE MDA WOULD NOT BE COMPROMISED IF THERE WERE NO PRE-EMPTION.

Petitioner asserts that, absent pre-emption, manufacturers will be compelled to cease the development of potentially life-saving medical devices, and that such a result would undermine Congress' goal of promoting the advancement of medical technology.

The MDA was enacted "to provide for the safety and effectiveness of medical devices for human use." *Medtronic*, 116 S.Ct. at 2253. While Congress' desire to promote the development of medical technology was also a concern, the legislative history indicates that "any fears regarding regulatory burdens were related more to the risk of *additional* federal and state regulation rather than the danger of preexisting duties under common law." *Id.* (Emphasis in original.) Furthermore, any concern of protecting the industry was "far outweighed" by concern for the safety of those who use medical devices. *Id.*

Accordingly, public policy considerations do not warrant a finding of pre-emption.

CONCLUSION

The writ of certiorari should be denied.

Respectfully submitted,

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